

MAR 12 2004

510(k) SUMMARY

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Submitter's Name and Address:

Stanbio Laboratory Phone: (830) 249-0772
1261 North Main Street Fax: (830) 249-0851
Boerne, Texas 78006 e-mail: AOguchi@stanbio.com

Prepared By: Adaobi Oguchi
September 12, 2003

Product Name

Trade name: Direct LDL-Cholesterol Liquid Color®; Direct
HDL/LDL-Cholesterol Calibrator.

Common name: LDL-Cholesterol; Calibrator

Classification name: Lipoprotein test system; Calibrator.

Class: I;II

Product Code: ~~LBS~~ MKK, JIX

Manufacture: Stanbio Laboratory,
1261 North Main Street
Boerne, Texas 78006

The establishment Registration No. is 1616487.

Substantial Equivalence of Device

The Direct LDL-Cholesterol Liquid Color® and Direct HDL/LDL-Cholesterol Calibrator system (Stanbio) is substantially equivalent to LDL Cholesterol Plus (K012287) calibrated with HDL/LDL Cholesterol Plus Calibrator (Roche).

Description of Device

The device is a system using the reagent and calibrator in combination to directly measure the LDL-Cholesterol.

This is achieved by a homogenous method that directly measures serum LDL-Cholesterol levels without the need for any off-line pretreatment or centrifugation steps.

It employs a two-reagent system. The first reagent (R1) contains a combination of detergent, organic and inorganic phosphoric acid compounds, which specifically binds HDL, VLDL and chylomicrons leaving the LDL particles exposed.

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The second reagent (R2) contains enzymes, which then react with the LDL-cholesterol present in the sample.

Indications for use:

Direct LDL Cholesterol LiquiColor® and Direct HDL/LDL Cholesterol Calibrator system is a testing device for the quantitative determination of low-density lipoprotein cholesterol (LDL-C) in serum or plasma. LDL Cholesterol measurement aids the diagnosis and treatment of lipid and lipoprotein metabolism disorders.

Performance Data

Substantial equivalency was demonstrated by method comparison. Correlation study was performed between Direct LDL-Cholesterol Liquid Color®, calibrated with Direct HDL/LDL -Cholesterol Calibrator (Stanbio) and LDL Cholesterol Plus (K012287) calibrated with HDL/LDL Cholesterol Plus Calibrator (Roche) using 62 patient samples. A correlation coefficient of 0.9969 and a regression equation of $y = 1.025x - 4.0289$ was obtained.

Also, precision, linearity, sensitivity and interference studies were performed on Stanbio Direct LDL-Cholesterol Liquid Color®. Results of these tests were within acceptable range.

The result of LDL-cholesterol using Stanbio Direct LDL-Cholesterol Liquid Color® is linear to 700mg/dl.

For the analytical sensitivity, a change of 0.001 absorbance units is equivalent to approximately 0.4mg/dl of LDL Cholesterol.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 12 2004

Ms. Adaobi Oguchi
Quality Control Manager
Stanbio Laboratory
1261 North Main Street
Boerne, TX 78006

Re: k032936
Trade/Device Name: Stanbio Laboratory Direct LDL Cholesterol LiquiColor® and
Stanbio Direct HDL/LDL Cholesterol Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX; MRR
Dated: December 18, 2003
Received: December 22, 2003

Dear Ms. Oguchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

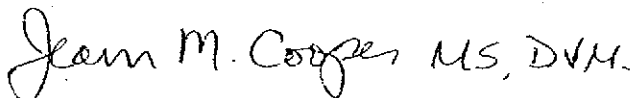
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "Jean M. Cooper MS, D.V.M.".

Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K032936

Device Name: Stanbio Laboratory Direct LDL Cholesterol LiquiColor® and Stanbio Direct HDL/LDL Cholesterol Calibrator

Indications for use:

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LDL Cholesterol measurement aids the diagnosis and treatment of lipid and lipoprotein metabolism disorders.

For In Vitro Diagnostic Use Only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR801.109)

OR

Over the Counter Use _____

Carol Benson
Division Sign-off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K032936

(Optional Format 1-2-96)